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October 13, 2004

Chicago District
550 West Jackson Blvd., 15th Floor
Chicago, Illinois 60661
Telephone: 312-353-5863

WARNING LETTER
CHI-1-05

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. James J. Flanigan
Acting President and Chief Operating Officer
Fischer Industries, Inc.
2630 Kaneville Court
Geneva, IL 60134

Dear Mr. Flanigan:

During inspection of your firm from August 4 to August 5, 2004, a United States Food and Drug Administration (FDA) investigator determined that your firm manufactures x-ray film processors. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

This inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation (QSR), Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Your firm failed to implement procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a). For example, your firm stopped using your established procedure for documenting complaints (SOP Q-052401-01) in 2002.
2. Your firm failed to establish and maintain procedures for implementing corrective and preventive action, as required by 21 CFR 820.100(a).
3. Your firm failed to establish and maintain procedures to control product that does not conform to specified requirements, as required by 21 CFR 820.90(a).
4. Your firm failed to maintain device history records, as required by 21 CFR 820.184. For example, your firm stopped documenting finished device inspection of x-ray processors in 2003.
5. Your firm failed to establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications, as required by 21 CFR 820.70(a).

6. Your firm failed to establish procedures to control the design of the device in order to ensure that specified design requirements are met, as required by 21 CFR 820.30.
7. Your firm failed to establish and conduct quality audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system, as required by 21 CFR 820.22.
8. Your firm failed to establish procedures, as required by 21 CFR 820.20(c), for management with executive responsibility to review the suitability and effectiveness of your quality system at defined intervals and with sufficient frequency, according to established procedures, to ensure that your quality system satisfies both the requirements of 21 CFR Part 820 (Quality System Regulation) and your firm's stated established quality policy and objectives.
9. Management with executive responsibility failed to appoint, and document such appointment of, a member of management, who irrespective of other responsibilities, shall have authority for ensuring that quality system requirements are effectively established and effectively maintained in accordance with 21 CFR Part 820 (Quality System Regulation) and reporting on the performance of the quality system to management with executive responsibility for review, as required by 21 CFR 820.20(b)(3).
10. Your firm failed to establish and maintain procedures to control documents, as required by 21 CFR 820.40.
11. Your firm failed to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements, as required by 21 CFR 820.50.
12. Your firm failed to establish procedures for identifying training needs and document training, as required by 21 CFR 820.25(b).

The Corrections and Removals Regulation (21 CFR Part 806) requires device manufacturers, distributors, and importers to keep records of corrections or removals that are not required to be reported to FDA under 21 CFR 806.10. Your firm's Model 3000 and 4000 series x-ray film processors are misbranded within the meaning of Section 502(t)(2) of the Act in that your firm failed to keep records, as required by 21 CFR 806.20, of the following field corrections that your firm implemented in 2000 and 2001, and were not required to be reported to FDA:

- Changing a temperature display that indicated "NPT Fail" although the device continued to function.
- Replacement of a microprocessor-circuit board combination with a microprocessor due to cracking solder joints.
- Replacement of a film-feed switch with a switch that was more robust and sealed to protect from chemical splashes.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Form FDA-483, Inspectional Observations, issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the FDA. You should promptly initiate permanent corrective and preventive action on your quality system.

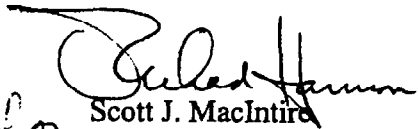
Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. No premarket submissions for Class III devices, to which the QSR deficiencies are reasonably related, will be cleared or approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected and verified.

You should take prompt action to correct these deviations and to establish procedures to prevent their recurrence. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office, in writing, within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including (1) the time frames within which the corrections will be completed, (2) any documentation indicating that the corrections have been achieved, and (3) an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur.

Your response should be sent to Michael Lang, Compliance Officer, Food and Drug Administration. If you have any questions regarding this letter, please contact Mr. Lang at (312) 596-4225.

Sincerely,


for Scott J. MacIntire
District Director